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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,287	12/31/2003	Jane Frances Heschmeyer	08116.0023.NPUS00	9611
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Steven J. Moore			STULII, VERA	
Kelley Drye & Warren LLP				
Intellectual Property Department			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,287	Applicant(s) HESCHMEYER ET AL.
	Examiner VERA STULII	Art Unit 1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 September 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5,14,15 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,5,14,15 and 18-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 14-15, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The meaning of the term "pre-cooked" is not clear. It is not clear what exactly is being pre-cooked (i.e. the starch itself, starched mixed with water, mixture of starches, or there is some other interpretation). There appears to be no further description of what this means or what condition one employs to define the "pre-cooked" term. Also, the context of the phrase "pre-cooked" itself is not clear. "Pre" means before. It is not clear at what point the mixture was pre-cooked. It is also not clear what is the relationship of "pre-cooking" to the actual cooking step to form the wafer.

Response to Arguments

Applicant's arguments, regarding the above rejection, filed September 17, 2008, have been fully considered but they are not persuasive. On page 9 of the remarks applicants state that:

The term "pre-cooked" is clearly defined on page 2 of the specification, at 2nd paragraph, where it is stated that "...the present invention includes a

Art Unit: 1794

low gluten wafer including about 1.0 part wheat starch, about 1.0 part pre-gelatinized wheat starch, where the wheat starch and pre-gelatinized wheat starch are combined into a substantially homogenous mixture. The low gluten wafer also includes about 2.0 parts of water having a temperature between about room temperature to about 212 degrees Fahrenheit, where the water is combined with substantially homogenous mixture of wheat starch and pre-gelatinized wheat starch until the entire mixture is substantially homogenous to create a "pre-cooked" mixture. From this description it is clear that the "pre-cooked" mixture is composed of 1.0 part wheat starch, about 1.0 part pre-gelatinized wheat starch, and about 2.0 parts of water, whereby the water has a temperature between about room temperature to about 212 degrees Fahrenheit.

Applicants' arguments are not deemed persuasive for the reasons as stated in the rejection above. The meaning of the term "pre-cooked" is still not clear. It appears that no actual cooking as application of heat is involved in preparation of so-called "pre-cooked" mixture. The "pre-cooked mixture" is merely a mix of starches and water at about room temperature or higher.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 14-15 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear as to how the "pre-cooked" as it exists can contain water at the recited temperature.

The meaning of the term "pre-cooked" is not clear. It is not clear what exactly is being pre-cooked (i.e. the starch itself, starched mixed with water, mixture of starches, or there is some other interpretation). Also, the context of the phrase "pre-cooked" itself is not clear. "Pre" means before. It is not clear at what point mixture was pre-cooked. It is also not clear what is the relationship of "pre-cooking" to the actual cooking step to form the wafer.

Response to Arguments

Applicant's arguments, regarding the above rejection, filed September 17, 2008, have been fully considered but they are not persuasive. On page 10 of the remarks applicants state that:

Regarding the Examiner's question of how the "pre-cooked" mixture as it exists can contain water at the recited temperature, the Applicants respectfully point out first of all that this mixture need not exist for any length of time with the water being at the claimed temperature, it is only during production of this mixture that the mixture contains water at this temperature, i.e., water at this temperature is added to the mixture of wheat starch and pre-gelatinized wheat starch.

Applicants' arguments are not deemed persuasive for the reasons as stated in the rejection above. The claim, as currently written, does not reflect the fact that water having recited temperature is being added to the starches. It is not clear as to how the "pre-cooked" mixture as it exists can contain water at the recited temperature, since applicant does not recite that the mixture as claimed is at initial moment of production.

Applicants' arguments are not deemed persuasive for the reasons as stated in the rejections of claims 1, 5, 14-15, and 18-20 under 35 U.S.C. 112, first and second paragraph above.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1, 5, 14-15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wernecke (DE 1927394) in view of applicants' prior art admission for the reasons of record stated in the Office action mailed March 17, 2008.

Response to Arguments

Applicant's arguments filed September 17, 2008 have been fully considered but they are not persuasive.

On page 12 of the remarks applicants state that:

The applicants respectfully submit that the reference cited by the Examiner does not disclose a mixture composed *only* of these ingredients, but one that has additional ingredients.

In addition, contrary to the Examiner's opinion, Wernecke (DE 1927394) reference does not mention that the mixture contains water, i.e., it is simply a dry mixture to which water may be added at some later time.

Furthermore, from the reference cited by the Examiner (Wernecke, DE 1927394), it is obvious that proportion of the pregelatinised wheat starch is clearly less than 10%.

For the reason described above, the Applicants respectfully submit that the stock mixture as set forth in independent claim 1 is not disclosed in the prior art of record (Wernecke (DE 1927394).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As stated in the rejection of record (Office action mailed March 17, 2008), Wernecke discloses a low-gluten bread for low-protein diets that contains maximum 0.3% by weight gluten (Abstract). Wernecke also discloses the bread product comprising wheat starch, pregelatinised wheat starch and water (Abstract, p.5 bottom paragraph of original document). Wernecke discloses that pregelatinised wheat starch serves as a structure improving component (Translation p.3). Wernecke also discloses baking at a temperature of 400F (Translation p.5). Wernecke also discloses dry mixture containing 86.69% of wheat starch component, 7.08% of sugar, 6.23 % of fat to which water and yeast is added to form a homogeneous mixture (p. 7 of the original document). Claim 1 differs from the Wernecke reference in reciting the mixture contains only wheat starch, pregelatinised wheat starch and water. Wernecke is not seen to be only limited to bread, but rather is seen to be a generic teaching applicable to any wheat based product wherein one is desirous of providing a low protein (i.e., low gluten) product. To modify Wernecke and eliminate other conventional ingredients such as sugar and fat and their well known function and employ only wheat starch, pregelatinised wheat starch and water, is seen to have been an obvious function, obviously dependent on the type of conventional gluten containing product one chooses to make and the flavor and texture one chooses to impart to the product. Applicants

admission of the prior art acknowledges that a communion wafer is made from only wheat and water (Specification page 1). Applicant is also making a communion wafer. Wernecke discloses low-gluten bread product, where flour is substituted with starches such as wheat starch and pregelatinised wheat starch. As admitted by Applicants, it was well known in the art that traditional communion wafers served during Roman Catholic Communion services are made out of two ingredients, wheat flour (wheat component) and water. Since Wernecke discloses low-gluten bread product for people suffering from Celiac disease by using wheat starch and pregelatinised wheat starch as a wheat component instead of flour, one of ordinary skill in the art would have been motivated to modify the disclosure of Wernecke and to employ wheat starch and pregelatinised wheat starch as the wheat component in preparation of communion wafers to produce a low gluten communion wafer. One of ordinary skill in the art would have been motivated to do so, since using water and wheat component in preparation of communion wafers was a well established fact in the art. As disclosed, Applicants' reasons for using starches is to provide a product which is designed for people suffering from celiac disease. As evidenced by Wernecke it was well known in the art to provide edible food products that have starch substitute for flour to provide low-gluten product for people suffering from celiac disease. Wernecke recognizes Applicants' problem and solution. Wernecke also discloses production of "very well tasting bread" and use of other ingredients than only wheat starch, pregelatinised wheat starch and water (page 1 of Translation, Abstract). As admitted by Applicants, it was well known in the art that traditional communion wafers served during Roman Catholic Communion services are

Art Unit: 1794

made out of two ingredients, wheat flour (wheat component) and water. Therefore to produce the communion wafer by using wheat starch ingredients and water, and to eliminate additional ingredients disclosed in Wernecke would have been obvious to one of ordinary skill in the art. Since Wernecke discloses that pregelatinised wheat starch serves as a structure improving component, one of ordinary skill in the art would have been motivated to vary amounts of starches in the mixture depending on the desired properties of the final product. The art taken as a whole therefore fairly teaches to modify Wernecke and substitute one conventional wheat based product and its conventional ingredients for another conventional wheat based product and its conventional ingredients, while maintaining the wheat starch and pregelatinised wheat starch mixture to produce a low gluten product. It would also have been equally obvious to modify applicants admission of the prior art, which teaches a communion wafer comprising wheat flour (a wheat component) and water, and substitute a wheat starch and pregelatinised wheat starch mixture for the wheat flour to provide a low gluten communion wafer in view of Wernecke.

Therefore, specifically regarding applicants' argument, that "the reference cited by the Examiner does not disclose a mixture composed only of these ingredients, but one that has additional ingredients", it is noted that as admitted by Applicants, it was well known in the art that traditional communion wafers served during Roman Catholic Communion services are made out of two ingredients, wheat flour (wheat component) and water. Since Wernecke discloses low-gluten bread product for people suffering from Celiac disease by using wheat starch and pregelatinised wheat starch as a wheat

Art Unit: 1794

component, one of ordinary skill in the art would have been motivated to modify disclosure of Wernecke and to employ wheat starch and pregelatinised wheat starch as a wheat component in preparation of communion wafers. One of ordinary skill in the art would have been motivated to do so, since using water and wheat component in preparation of communion wafers was a well established fact in the art.

Further specifically regarding applicants' argument, that "[i]n addition, contrary to the Examiner's opinion, Wernecke (DE 1927394) reference does not mention that the mixture contains water, i.e., it is simply a dry mixture to which water may be added at some later time", applicant is referred to pages 5 and 10 the original document where Wernecke discloses addition of water to the dry mixture comprising starches.

Further specifically regarding applicants' argument, that "[f]urthermore, from the reference cited by the Examiner (Wernecke, DE 1927394), it is obvious that proportion of the pregelatinised wheat starch is clearly less than 10%", it is noted that Wernecke discloses dry mixture containing 86.69% of wheat starch component (p. 7 of the original document). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., percentage of pregelatinised wheat starch) are not recited in the rejected claim(s). In any case, once it was known to employ a mixture of wheat starch and pregelatinised wheat starch as a substitute for wheat flour to produce a low gluten product, the particular concentrations of the ingredients is seen to have been an obvious result effective variable routinely determinable. Although the claims are interpreted in light of

the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VERA STULII whose telephone number is (571)272-3221. The examiner can normally be reached on 7:00 am-3:30 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1794

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steve Weinstein/
Primary Examiner, Art Unit 1794

VS